CLAIM AMENDMENTS

1. (Currently Amended) A sustained release dosage form of an anesthetic comprising: a short duration gel vehicle comprising a low molecular weight bioerodible, biocompatible polymer and a water-immiscible solvent in an amount effective to plasticize the polymer and form a gel therewith; and an anesthetic dissolved or dispersed in the gel vehicle, wherein said anesthetic is selected from the group consisting of: bupivacaine, levo-bupivacaine, ropivacaine, levo-ropivacaine, tetracaine, etidocaine, levo-etidocaine, dextro-etidocaine, levo-etidocaine, dextro-etidocaine, levo-mepivacaine, and combinations thereof, and further wherein the dosage form provides for a reduced initial burst of the anesthetic from the dosage form after local administration.

2. (Original) The sustained release dosage form of claim 1 further comprising a controllable efficacy ratio to achieve a release profile.

3. (Original) The sustained release dosage form of claim 2 wherein the efficacy ratio is between about 1 and 200.

4. (Original) The sustained release dosage form of claim 3 wherein the efficacy ratio is between about 5 and 100.

5. (Original) The sustained release dosage form of claim 1 wherein the sustained release occurs in a period of less than or equal to about fourteen days.

6. (Original) The sustained release dosage form of claim 5 wherein the sustained release occurs in a period of less than or equal to about seven days.

7. (Original) The sustained release dosage form of claim 6 wherein the sustained release lasts for a period of between about 24 hours and about seven days.

8. (Currently Amended) The sustained release dosage form of claim 1 wherein the anesthetic is selected from the group consisting of: bupivacaine, levo-bupivacaine, ropivacaine, levo-ropivacaine, tetracaine, ~~etidocaine, levo-etidocaine, dextro-etidocaine, levo-etidocaine, dextro-etidocaine, levo-mepivacaine,~~ and combinations thereof.

9. (Original) The sustained release dosage form of claim 1 wherein the anesthetic comprises bupivacaine.

10. (Original) The sustained release dosage form of claim 1 wherein the solvent has a miscibility in water of less than or equal to about 7 weight % at 25.degree. C.

11. (Original) The sustained release dosage form of claim 1 wherein the dosage form is free of solvents having a miscibility in water that is greater than 7 weight % at 25° C.

12. (Original) The sustained release dosage form of claim 1 wherein the solvent is selected from the group consisting of: an aromatic alcohol, lower alkyl esters of aryl acids, lower aralkyl esters of aryl acids, aryl ketones, aralkyl ketones, lower alkyl ketones, lower alkyl esters of citric acid, and combinations thereof.

13. (Original) The sustained release dosage form of claim 1 wherein the solvent comprises benzyl alcohol.

14. (Withdrawn) The sustained release dosage form of claim 1 wherein the solvent comprises benzyl benzoate.

15. (Withdrawn) The sustained release dosage form of claim 1 wherein the solvent comprises ethyl benzoate.

16. (Withdrawn) The sustained release dosage form of claim 1 wherein the solvent

comprises triacetin.

17. (Currently Amended) The sustained release dosage form of claim 1 ~~wherein the solvent comprises~~ further comprising a component solvent selected from the group consisting of: triacetin, diacetin, tributyrin, triethyl citrate, tributyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, triethylglycerides, triethyl phosphate, diethyl phthalate, diethyl tartrate, mineral oil, polybutene, silicone fluid, glylcerin, ethylene glycol, polyethylene glycol, octanol, ethyl lactate, propylene glycol, propylene carbonate, ethylene carbonate, butyrolactone, ethylene oxide, propylene oxide, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol formal, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, and 1-dodecylazacyclo-heptan-2-one, and combinations thereof.

18. (Original) The sustained release dosage form of claim 1 wherein the polymer comprises a lactic acid-based polymer.

19. (Original) The sustained release dosage form of claim 18 wherein the polymer comprises a copolymer of lactic acid and glycolic acid (PLGA).

20. (Original) The sustained release dosage form of claim 19 wherein the copolymer has a monomer ratio of lactic acid to glycolic acid of approximately 50:50.

21. (Withdrawn) The sustained release dosage form of claim 1 wherein the polymer comprises a caprolactone-based polymer.

22. (Original) The sustained release dosage form of claim 1 wherein the polymer is selected from the group consisting of: polylactides, polyglycolides, poly(caprolactone), polyanhydrides, polyamines, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyphosphoesters, polyesters, polybutylene

terephthalate, polyorthocarbonates, polyphosphazenes, succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, polysaccharides, chitin, chitosan, hyaluronic acid, and copolymers, terpolymers and mixtures thereof.

23. (Original) The sustained release dosage form of claim 19 wherein the polymer comprises an ester end group.

24. (Original) The sustained release dosage form of claim 19 wherein the polymer comprises a carboxylic acid end group.

25. (Original) The sustained release dosage form of claim 1 wherein the polymer has a weight average molecular weight of between about 3,000 and about 10,000.

26. (Original) The sustained release dosage form of claim 25 wherein the polymer has a weight average molecular weight of between about 3,000 and about 8,000.

27. (Original) The sustained release dosage form of claim 26 wherein the polymer has a weight average molecular weight of between about 4,000 and about 6,000.

28. (Original) The sustained release dosage form of claim 27 wherein the polymer has a weight average molecular weight of about 5,000.

29. (Original) The sustained release dosage form of claim 1 wherein the dosage form comprises from about 0.1% to about 50% anesthetic by weight.

30. (Original) The sustained release dosage form of claim 29 wherein the dosage form comprises from about 0.5% to about 40% anesthetic by weight.

31. (Original) The sustained release dosage form of claim 30 wherein the dosage

form comprises from about 1% to about 30% anesthetic by weight.

32. (Original) The sustained release dosage form of claim 1 wherein the ratio between the polymer and the solvent is between about 5:95 and about 90:10.

33. (Original) The sustained release dosage form of claim 32 wherein the ratio between the polymer and the solvent is between about 20:80 and about 80:20.

34. (Original) The sustained release dosage form of claim 33 wherein the ratio between the polymer and the solvent is between about 30:70 and about 75:25.

35. (Original) The sustained release dosage form of claim 1 further comprising at least one of the following: an excipient, an emulsifying agent, a pore former, a solubility modulator for the anesthetic, and an osmotic agent.

36. (Original) The sustained release dosage form of claim 1 wherein the anesthetic comprises particles having an average particle size of less than about 250 μm.

37. (Original) The sustained release dosage form of claim 36 wherein the anesthetic comprises particles having an average particle size of between about 5 μm and 250 μm.

38. (Original) The sustained release dosage form of claim 37 wherein the average particle size is between about 20 μm and about 125 μm.

39. (Original) The sustained release dosage form of claim 38 wherein the average particle size is between about 38 μm and about 63 μm.

40. (Original) A sustained release dosage form of an anesthetic comprising: a short duration gel vehicle comprising a low molecular weight lactic acid-based polymer

and a water-immiscible solvent, in an amount effective to plasticize the polymer and form a gel therewith; an anesthetic comprising bupivacaine, wherein the anesthetic is dissolved or dispersed in the gel vehicle; and a controllable efficacy ratio to achieve a release profile; wherein the weight average molecular weight of the lactic acid-based polymer is between about 3,000 and about 10,000.

41. (Original) The sustained release dosage form of claim 40 wherein the sustained release occurs in a period of less than or equal to about fourteen days.

42. (Original) The sustained release dosage form of claim 41 wherein the sustained release occurs in a period of less than or equal to about seven days.

43. (Original) The sustained release dosage form of claim 42 wherein the sustained release lasts for a period of between about 24 hours and about seven days.

44. (Original) The sustained release dosage form of claim 40 wherein the efficacy ratio is between about 1 and about 200.

45. (Original) The sustained release dosage form of claim 44 wherein the efficacy ratio is between about 5 and about 100.

46. (Original) The sustained release dosage form of claim 40 wherein the polymer comprises a copolymer of lactic acid and glycolic acid (PLGA).

47. (Original) The sustained release dosage form of claim 46 wherein the copolymer has a monomer ratio of lactic acid to glycolic acid of approximately 50:50.

48. (Original) The sustained release dosage form of claim 46 wherein the copolymer comprises poly(D,L-lactide-co-glycolide).

49. (Original) The sustained release dosage form of claim 46 wherein the copolymer comprises poly(L-lactide-co-glycolide).

50. (Original) The sustained release dosage form of claim 40 wherein the solvent has a miscibility in water of less than or equal to about 7 weight % at 25°C.

51. (Original) The sustained release dosage form of claim 40 wherein the dosage form is free of solvents having a miscibility in water that is greater than 7 weight % at 25°C.

52. (Original) The sustained release dosage form of claim 40 wherein the solvent is selected from the group consisting of: an aromatic alcohol, lower alkyl esters of aryl acids, lower aralkyl esters of aryl acids; aryl ketones, aralkyl ketones, lower alkyl ketones, lower alkyl esters of citric acid, and combinations thereof.

53. (Original) The sustained release dosage form of claim 40 wherein the solvent comprises benzyl alcohol.

54. (Withdrawn) The sustained release dosage form of claim 40 wherein the solvent comprises benzyl benzoate.

55. (Withdrawn) The sustained release dosage form of claim 40 wherein the solvent comprises ethyl benzoate.

56. (Withdrawn) The sustained release dosage form of claim 40 wherein the solvent comprises triacetin.

57. (Original) The sustained release dosage form of claim 40 wherein the polymer has a weight average molecular weight of between about 3,000 and 8,000.

58. (Original) The sustained release dosage form of claim 57 wherein the polymer has a weight average molecular weight of between about 4,000 and 6,000.

59. (Original) The sustained release dosage form of claim 58 wherein the polymer has a weight average molecular weight of about 5,000.

60. (Original) The sustained release dosage form of claim 40 wherein the dosage form comprises from about 0.1% to about 50% anesthetic by weight.

61. (Original) The sustained release dosage form of claim 60 wherein the dosage form comprises from about 0.5% to about 40% anesthetic by weight.

62. (Original) The sustained release dosage form of claim 61 wherein the dosage form comprises from about 1% to about 30% anesthetic by weight.

63. (Original) The sustained release dosage form of claim 62 wherein the ratio between the polymer and the solvent is between about 5:95 and about 90:10.

64. (Original) The sustained release dosage form of claim 63 wherein the ratio between the polymer and the solvent is between about 20:80 and about 80:20.

65. (Original) The sustained release dosage form of claim 64 wherein the ratio between the polymer and the solvent is between about 30:70 and about 75:25.

66. (Original) The sustained release dosage form of claim 40 wherein the anesthetic comprises particles having an average particle size of less than about 250 μm.

67. (Original) The sustained release dosage form of claim 66 wherein the anesthetic comprises particles having an average particle size of between about 5 μm and about 250 μm.

68. (Original) The sustained release dosage form of claim 67 wherein the average particle size is between about 20 μm and about 125 μm.

69. (Original) The sustained release dosage form of claim 68 wherein the average particle size is between about 38 μm and about 63 μm.

70. (Original) The sustained release dosage form of claim 46 wherein the PLGA comprises an ester end group.

71. (Original) The sustained release dosage form of claim 46 wherein the PLGA comprises a carboxyl end group.

72. (Original) The sustained release dosage form of claim 40 further comprising at least one of the following: an excipient, an emulsifying agent, a pore former, a solubility modulator for the anesthetic, and an osmotic agent.

73. (Withdrawn) A method of treating local pain of a subject using a sustained release dosage form, the method comprising: administering a short duration sustained release dosage form comprising a gel vehicle, which comprises a low molecular weight bioerodible, biocompatible polymer, and a water-immiscible solvent in an amount effective to plasticize the polymer and form a gel therewith; and an anesthetic dissolved or dispersed in the gel vehicle.

74. (Withdrawn) The method of claim 73 wherein the sustained release dosage form further comprises a controllable efficacy ratio to achieve a release profile.

75. (Withdrawn) The method of claim 74 wherein the efficacy ratio is between about 1 and 200.

76. (Withdrawn) The method of claim 75 wherein the efficacy ratio is between about 5 and 100.

77. (Withdrawn) The method of claim 73 wherein the sustained release occurs in a period of less than or equal to about fourteen days.

78. (Withdrawn) The method of claim 77 wherein the sustained release occurs in a period of less than or equal to about seven days.

79. (Withdrawn) The method of claim 78 wherein the sustained release lasts for a period of between about 24 hours and about seven days.

80. (Withdrawn) The method of claim 73 further comprising administering the dosage form once.

81. (Withdrawn) The method of claim 73 further comprising applying the dosage form topically to the local pain.

82. (Withdrawn) The method of claim 73 further comprising injecting the dosage form at a location near the local pain.

83. (Withdrawn) The method of claim 73 further comprising delivering the anesthetic systemically.

84. (Withdrawn) The method of claim 73 further comprising delivering the anesthetic to multiple sites.

85. (Withdrawn) The method of claim 84 further comprising delivering injecting the dosage form at multiple locations surrounding the local pain.

86. (Withdrawn) The method of claim 73 further comprising repeating the administration of the dosage form.

87. (Withdrawn) The method of claim 73 wherein the anesthetic is selected from the group consisting of: bupivacaine, levo-bupivacaine, ropivacaine, levo-ropivacaine, tetracaine, etidocaine, levo-etidocaine, dextro-etidocaine, levo-etidocaine, dextro-etidocaine, levo-mepivacaine, and combinations thereof.

88. (Withdrawn) The method of claim 73 wherein the anesthetic comprises bupivacaine.

89. (Withdrawn) The method of claim 73 wherein the has a miscibility in water of less than or equal to about 7 weight % at 25°C.

90. (Withdrawn) The method of claim 73 wherein the polymer has a molecular weight of between about 3,000 and 10,000.

91. (Withdrawn) The method of claim 90 wherein the polymer has a weight average molecular weight of between about 3,000 and 8,000.

92. (Withdrawn) The method of claim 91 wherein the polymer has a weight average molecular weight of between about 4,000 and 6,000.

93. (Withdrawn) The method of claim 92 wherein the polymer has a weight average molecular weight of about 5,000.

94. (Withdrawn) The method of claim 73 wherein the dosage form comprises from about 0.1 to about 50% anesthetic by weight.

95. (Withdrawn) The method of claim 73 wherein the polymer is selected from the

group consisting of: polylactides, polyglycolides, poly(caprolactone), polyanhydrides, polyamines, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyphosphoesters, polyesters, polybutylene terephthalate, polyorthocarbonates, polyphosphazenes, succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, polysaccharides, chitin, chitosan, hyaluronic acid, and copolymers, terpolymers and mixtures thereof.

96. (Withdrawn) The method of claim 73 wherein the sustained release dosage form comprises a ratio of about 5:95 and about 90:10 between the polymer and the solvent.

97. (Withdrawn) The method of claim 73 wherein the anesthetic comprises particles having an average particle size of less than about 250 μm.

98. (Withdrawn) A method of treating post-surgical local pain of a subject using a sustained release dosage form, the method comprising: administering once a short duration sustained release dosage form comprising a gel vehicle, which comprises a low molecular weight bioerodible, biocompatible lactic acid-based polymer, and a water-immiscible solvent in an amount effective to plasticize the polymer and form a gel therewith; an anesthetic comprising bupivacaine dissolved or dispersed in the gel vehicle; and a controllable efficacy ratio to achieve a release profile.

99. (Withdrawn) The method of claim 98 wherein the polymer comprises a copolymer of lactic acid and glycolic acid (PLGA).

100. (Withdrawn) The method of claim 99 wherein the copolymer has a monomer ratio of lactic acid to glycolic acid of approximately 50:50.

101. (Withdrawn) A method of preparing a sustained release dosage form, the method comprising: preparing a short duration gel vehicle comprising a low molecular weight bioerodible, biocompatible polymer and a water-immiscible solvent in an amount

effective to plasticize the polymer and form a gel therewith to create a polymer/solvent solution or gel; equilibrating the polymer/solvent mixture until a clear homogeneous solution or gel is achieved; dissolving or dispersing an anesthetic into the polymer/solvent solution or gel; blending the anesthetic and the polymer/solvent solution or gel to form a sustained release dosage form; and controlling an efficacy ratio to achieve a release profile.

102. (Withdrawn) The method of claim 101 wherein the efficacy ratio is between about 1 and 200.

103. (Withdrawn) The method of claim 101 wherein the polymer/solvent solution or gel is equilibrated at a temperature between room temperature and approximately 65°C.

104. (Withdrawn) The method of claim 101 wherein the anesthetic comprises bupivacaine.

105. (Withdrawn) The method of claim 101 wherein the anesthetic is selected from the group consisting of: bupivacaine, levo-bupivacaine, ropivacaine, levo-ropivacaine, tetracaine, etidocaine, levo-etidocaine, dextro-etidocaine, levo-etidocaine, dextro-etidocaine, levo-mepivacaine, and combinations thereof.

106. (Withdrawn) The method of claim 101 wherein the polymer comprises a lactic acid-based polymer.

107. (Withdrawn) The method of claim 106 wherein the polymer comprises a copolymer of lactic acid and glycolic acid (PLGA).

108. (Withdrawn) The method of claim 107 wherein the copolymer has a monomer ratio of lactic acid to glycolic acid of approximately 50:50.

109. (Withdrawn) The method of claim 107 wherein the polymer comprises poly(D,L-lactide-co-glycolide).

110. (Withdrawn) The method of claim 107 wherein the polymer comprises poly(L-lactide-co-glycolide).

111. (Withdrawn) The method of claim 101 comprising loading the dosage form with from about 0.1% to about 50% anesthetic by weight of the dosage form.

112. (Withdrawn) The method of claim 111 comprising loading the dosage form with from about 0.5% to about 40% anesthetic by weight of the dosage form.

113. (Withdrawn) The method of claim 112 comprising loading the dosage form with from about 1% to about 30% anesthetic by weight of the dosage form.

114. (Withdrawn) The method of claim 101 comprising providing a ratio of about 5:95 and about 90:10 between the polymer and the solvent.

115. (Withdrawn) The method of claim 114 comprising providing a ratio of about 20:80 and about 80:20 between the polymer and the solvent.

116. (Withdrawn) The method of claim 115 comprising providing a ratio of about 30:70 and about 75:25 between the polymer and the solvent.

117. (Withdrawn) The method of claim 101 wherein the solvent is selected from the group consisting of: an aromatic alcohol, lower alkyl esters of aryl acids, lower aralkyl esters of aryl acids; aryl ketones, aralkyl ketones, lower alkyl ketones, lower alkyl esters of citric acid, and combinations thereof.

118. (Withdrawn) The method of claim 107 wherein the PLGA comprises an ester

end group.

119. (Withdrawn) The method of claim 107 wherein the PLGA comprises a carboxyl end group.

120. (Withdrawn) The method of claim 101 further comprising adding at least one of the following to the dosage form: an excipient, an emulsifying agent, a pore former, a solubility modulator for the anesthetic, and an osmotic agent.

121. (Withdrawn) The method of claim 101 wherein the anesthetic comprises particles having an average particle size of less than about 250 μm.

122. (Original) A kit for administration of a sustained delivery of an anesthetic to local pain of a subject comprising: a short duration gel vehicle comprising a low molecular weight bioerodible, biocompatible polymer and a water-immiscible solvent, in an amount effective to plasticize the polymer and form a gel therewith; an anesthetic dissolved or dispersed in the gel vehicle; and optionally, one or more of the following: an excipient; an emulsifying agent; a pore former; a solubility modulator for the anesthetic, optionally associated with the anesthetic; and an osmotic agent; wherein at the least anesthetic agent, optionally associated with the solubility modulator, is maintained separated from the solvent until the time of administration of the anesthetic to the subject.